K122171

OSSTEM Implant Co., Ltd.
#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804 Republic of Korea
Tel: +82 51 850-2500 Fax: +82 51 850-4341 www.osstem.com

510(k) Summary

NOV 16 2012

This summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: July 13, 2012

1. Company and Correspondent making the submission:

- Submitter's Name :	OSSTEM Implant Co., Ltd.
- Address :	#507-8 Geoje3-Dong Yeonje-Gu Busan, 611-804, Republic of Korea
- Contact :	Mr. Hee Kwon Son
- Phone:	+82 51 850 2575
- Correspondent's Name:	HIOSSEN Inc.
- Address:	85 Ben Fairless Dr. Fairless Hills, PA 19030
- Contact:	Patrick Lim
- Phone:	888 678 0001

2. Device :

Trade or (Proprietary) Name :	MS SA Implant System
Common or usual name :	Dental Implant
Classification Name :	Endosseous Dental Implant 21CFR872.3640 Class II DZE

3. Predicate Device:

MS System, OSSTEM Implant Co., Ltd, K083067
Straumann Dental Implants, Institut Straumann AG, K061176

4. Description:

The MS SA Implant System is a dental implant made of titanium alloy (Ti-6Al-4V) metal. The MS SA Implant System is similar to other commercially available products based on the intended use, the technology used, the claims, the material composition employed and performance characteristics. The surface treatment of MS SA Implant System is SA (Sandblasting and Acid etching).

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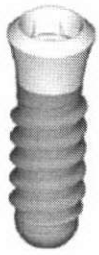
The MS SA Implant System is substantially equivalent in design, function and intended use to the MS System, OSSTEM Implant Co., Ltd, K083067

The MS SA Implant System is substantially equivalent in surface treatment to the Straumann Dental Implants, Institut Straumann AG, K061176

- Substantial Equivalence Matrix

	MS SA Implant System (Narrow Ridge)	Predicate devices	
		MS System (Narrow Ridge)	Straumann Dental Implants
Design			
510(K) No.	New device	K083067	K061176
Intended use	The MS SA Implant (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The MS SA Implant (Narrow Ridge) is intended for single use only. It is intended for delayed loading.	The MS System (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. MS System (Narrow Ridge) are intended for single use only.	Straumann Regular Neck and Narrow Neck implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, four or more implants must be used. The Straumann Regular Neck Implants are intended for surgical placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients for single-stage or two-stage

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			surgery. The Straumann Narrow Neck implants are intended for surgical placement in the maxilla or mandible to serve as a base for prosthetic reconstructions. Specifically, the Narrow Neck implant is indicated for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. It is particularly intended for those areas where the interdental space is extremely limited (minimum 5 mm) and where vestibule-oral bone is restricted (minimum 5 mm). The Narrow Neck implant can also be used as a support for a full arch implant-born restoration, but only in conjunction with a standard Straumann 4.1 mm dental implant.
Structure	- SA(Sandblasting and Acid etching). - Threaded Body Design - One Body Implant	- R.B.M (Resorbable Blasting Media). - Micro Thread Design. - Threaded Body Design - One Body Implant	-Single Thread -Straight body Type -Non-submerged fixture
Thread body Diameter (D)	2.5, 2.9	2.5, 3.0	3.3~4.8
Length (mm) of thread	8.5, 10.0, 11.5, 13.0	8.5, 10.0, 11.5, 13.0, 15.0	6.0~16.0
Material of Fixture	Titanium alloy Ti-6Al-4V (ASTM F 136)	Titanium alloy Ti-6Al-4V (ASTM F 136)	Pure Titanium Grade 4 (ASTM F67)
Surface	SA(Sandblasting and Acid etching).	R.B.M (Resorbable Blasting Media).	SLA(Grit blasting, acid etched SLA surface)
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
S E	The MS SA Implant System (Narrow Ridge) has the same material, indication for use and similar design as the MS System (Narrow Ridge) (K083067) except surface treatment. but the surface treatment of The MS SA Implant System (Narrow Ridge) is the similar with surface treatment of Straumann Dental Implants (K061176)		

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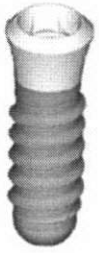
	MS SA Implant System (Denture)	Predicate devices	
		MS System (Denture)	Straumann Dental Implants
Design			
510(K) No.	New device	K083067	K061176
Intended use	The MS SA Implant (Denture) is intended to be placed in the bone of the upper or lower jaw arches to provide support of the prosthetic devices to restore the patient's chewing function, including the denture stabilization. The MS SA Implant (Denture) is intended for single use only.	The MS System (Denture) is intended to be place in the bone of the upper or lower jaw arches to provide support the prosthetic devices to restore the patient's chewing function, including the denture stabilization. MS System (Denture) is intended for single use only.	Straumann Regular Neck and Narrow Neck implants are intended for immediate placement and function on single-tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth applications may be rigidly splinted. In the case of edentulous patients, four or more implants must be used. The Straumann Regular Neck Implants are intended for surgical placement in the maxillary and/or mandibular arches to provide support for prosthetic restorations in edentulous or partially edentulous patients for single-stage or two-stage surgery. The Straumann Narrow Neck implants are intended for surgical placement in the maxilla or mandible to serve as a base for prosthetic reconstructions. Specifically, the Narrow

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			Neck implant is indicated for replacement of single lateral incisors in the maxilla and lateral and central incisors in the mandible. It is particularly intended for those areas where the interdental space is extremely limited (minimum 5 mm) and where vestibule-oral bone is restricted (minimum 5 mm). The Narrow Neck implant can also be used as a support for a full arch implant-born restoration, but only in conjunction with a standard Straumann 4.1 mm dental implant.
Structure	- SA(Sandblasting and Acid etching). - Ball-shaped suits for O-Ring attachment. - 2/4mm can be used according to gingival height. - Threaded Body Design	- R.B.M (Resorbable Blasting Media). - Ball-shaped suits for O-Ring attachment. - 2/4mm can be used according to gingival height. - Micro Thread Design. - Threaded Body Design	-Single Thread -Straight body Type -Non-submerged fixture
Thread body Diameter (D)	2.5, 2.9	2.0, 2.5, 3.0	3.3~4.8
Length (mm) of thread	8.5, 10.0, 11.5, 13.0	8.5, 11.5	6.0~16.0
Material of Fixture	Titanium alloy Ti-6Al-4V (ASTM F 136)	Titanium alloy Ti-6Al-4V (ASTM F 136)	Pure Titanium Grade 4 (ASTM F67)
Surface	SA(Sandblasting and Acid etching).	R.B.M (Resorbable Blasting Media).	SLA(Grit blasting, acid etched SLA surface)
Sterilization	Radiation Sterile	Radiation Sterile	Radiation Sterile
S E	The MS SA Implant System (Denture) has the same material, indication for use and similar design as the MS System (Denture) (K083067) except surface treatment. but the surface treatment of The MS SA Implant System (Denture) is the similar with surface treatment of Straumann Dental Implants (K061176)		

5. Indication for use:

The MS SA Implant (Denture) is intended to be placed in the bone of the upper or lower jaw arches to provide support of the prosthetic devices to restore the patient's chewing function, including the denture stabilization. The MS SA Implant (Denture) is intended for single use only.

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The MS SA Implant (Narrow Ridge) is intended to use in the treatment of missing mandibular central and lateral incisors to support prosthetic device, such as artificial teeth, in order to restore chewing function in partially edentulous patients. The MS SA Implant (Narrow Ridge) is intended for single use only. It is intended for delayed loading.

6. Review:

The MS SA Implant System has similar material, indication for use, design and technological characteristics as the predicate device.

The MS SA Implant System has been subjected to safety, performance, and product validations prior to release. Safety tests including biocompatibility have been performed to ensure the devices comply with the applicable International and US regulations.

7. Summary of nonclinical testing

Fatigue testing was considered according to the "Guidance for industry and FDA staff

Class II Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Abutment" with the worst case scenario of the MS SA Implant system

8. Summary of clinical testing
No clinical studies are submitted

9. Conclusions
In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Osstem Implant Co., Ltd. concludes that the MS SA Implant System is substantially equivalent to the predicate devices as described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

November 16, 2012

OSSTEM Implant Company, Limited
C/O Mr. Patrick Lim
Manager
HiOSSEN Incorporated
85 Ben Fairless Drive
Fairless Hills, Pennsylvania 19030

Re: K122171
Trade/Device Name: MS SA Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: II
Product Code: DZE
Dated: September 25, 2012
Received: September 28, 2012

Dear Mr. Lim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Anthony D. Watson, 0.9.2342.19200300.100.1.1=1300092402

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number K 122171

Device Name : MS SA Implant System

Indication for use : The MS SA Implant (Denture) is intended to be placed in the bone of the upper or lower jaw arches to provide support of the prosthetic devices to restore the patient's chewing function, including the denture stabilization. The MS SA Implant (Denture) is intended for single use only. It is intended for delayed loading.

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Prescription Use X (Per 21CFR801 Subpart D) OR Over-The-Counter Use _____. (Per 21CFR807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mary S. Runner

Digitally signed by Mary S. Runner
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Mary S. Runner, 0.9.2342.19200300.100.1.1=1300087950
Date: 2012.11.16 15:13:46 -05'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

510(k) Number: K122171